Title:- Evaluation of comparative efficacy of Trisamagutika versus Kshargutika in management of Tundikeri (chronic tonsillitis) in children: A Randomized Controlled Clinical Study

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Title:- Evaluation of comparative efficacy of Trisamagutika versus Kshargutika in management of Tundikeri (chronic tonsillitis) in children: A Randomized Controlled Clinical Study

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Abstract

Background: • Tonsillitis is more common in children between 5 to 15 years (more in 4 to 8 years.).There are 7,455,494 cases of tonsillitis and 2,00,000 tonsillectomies are performed in India per year. The incidence of this disease is about 7% of all visits to the paediatrician. Tundikeri is one of the Urdhwajatrugat Roga (diseases of Head and neck) mentioned by Acharya Sushrut, Vagbhata. Tonsillitis and Tundikeri can be correlated as both have the same features. Any infection in a growing child affects the immune system Repeated attacks of tonsillitis hampers routine growth and development also. Lastly, a radical cure for recurrent attacks is Tonsillectomy. Kshargutika from Charaksamhita is one of the formulations to treat kanthgat roga. The present study will be conducted to explore the efficacy of Kshargutika versus the efficacy of Trisamagutika in the management of chronic tonsilitis in children.

Objective: 1. To evaluate the comparative efficacy of Trisamagutika as standard control medicine versus Kshargutika in children with chronic tonsillitis on objective & Subjective parameters
2. To assess recurrence in terms of proportion in the reference of the control group (Trisamagutika) and trial group(Kshargutika).

Methods: Children with chronic Tonsillitis fulfilling inclusion criteria shall be randomly divided into two groups; 36 patients in each group. One group (P) will be given Trisamagutika and the other group (Q) will be given Kshargutika for 15 days orally B.D. Assessment will be done at 0,5,10 &15 th day. Followup will be taken every month for up to 1 year

Results: Results will be drawn on the observations of subjective parameters.

Conclusions: The conclusion of the study will be drawn based on statistical data calculated from the collected data. Clinical Trial: - CTRI No.- CTRI/2023/08/056542
Dated- 16/08/2023

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PROTOCOL ARTICLE

Title:- Evaluation of comparative efficacy of Trisamagutika versus Kshargutika in management of Tundikeri (chronic tonsillitis) in children: A Randomized Controlled Clinical Study

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Trial registration- CTRI No.- CTRI/2023/08/056542
Dated- 16/08/2023
Grant information-Not applied for any grant or funding

Abstract

Introduction:-

- Tonsillitis is more common in children between 5 to 15 years (more in 4 to 8 years.).There are 7,455,494 cases of tonsillitis and 2,00,000 tonsillectomies are performed in India per year. The incidence of this disease is about 7% of all visits to the paediatrician. Tundikeri is one of the Urdhwajatrugat Roga (diseases of Head and neck) mentioned by Acharya Sushrut, Vagbhata. Tonsillitis and Tundikeri can be correlated as both have the same features. Any infection in a growing child affects the immune system Repeated attacks of tonsillitis hampers routine growth and development also. Lastly, a radical cure for recurrent attacks is Tonsillectomy. Kshargutika from Charaksamhita is one of the formulations to treat kanthgat roga. The present study will be conducted to explore the efficacy of Kshargutika versus the efficacy of Trisamagutika in the management of chronic tonsilitis in children.

Aims & Objectives:- 1. To evaluate the comparative efficacy of Trisamagutika as standard control medicine versus Kshargutika in children with chronic tonsillitis on objective & Subjective parameters

2. To assess recurrence in terms of proportion in the reference of the control group (Trisamagutika) and trial group(Kshargutika).

Methodology:-

Children with chronic Tonsillitis fulfilling inclusion criteria shall be randomly divided into two groups; 36 patients in each group. One group (P) will be given Trisamagutika and the other group (Q) will be given Kshargutika for 15 days orally B.D. Assessment will be done at 0,5,10 &15 th day. Followup will be taken every month for up to 1 year.

Results:-Results will be drawn on the observations of subjective parameters.

Conclusion: The conclusion of the study will be drawn based on statistical data calculated from the collected data.

Keywords:-Tundikeri, Chronic Tonsillitis, Trisamagutika , Kshargutika.

Introduction:-Chronic tonsillitis is a regular and frequent complaint affecting approximately 10% of the population. Many new seasonal infections exist for children, but tonsillitis can occur throughout the year. It is more common in children between 5 to 15 years (more in 4 to 8 years.).[1]Specifically; in the bacterial tonsillitis group, A beta haemolytic streptococci (GABHS) prevalence is 15% to 30% of children with a sore throat, and in adults, with a sore throat, it is 5 to 15%.[2]

There are 7,455,494 cases of tonsillitis, and 2,00,000 tonsillectomies are performed in India per year.[3] In visits to the paediatrician, cases of Tonsillitis are 7%. The prevalence of tonsillitis in Maharashtra is 11.76%.[4]

Chronic Tonsillitis is described as when a patient suffers from acute tonsillitis attacks five or more than five times per year. Microorganisms that cause such recurrent infections create biofilms, and a repository infection in the warm and wet folds of the tonsils.[5]Clinical features of chronic Tonsillitis are recurrence, irritation in the throat, halitosis, dysphagia with choking spells at night.[5]

Diseases of the Head & Neck are called Urdhwajatrugat roga in Ayurveda. Tundikeri is one of the Urdhwajatrugat Roga mentioned by Acharya Sushrut and Vagbhata.[6,7] Tundi means mouth, and Keri means location. In Sushrutsamhita and Ashtanghridaya, characteristic features of tundikeri are sthool shotha (hard swelling), toda (pricking type of pain), daha (burning pain), prapaki (undergoes suppuration), avarodha (create an obstruction for respiration and deglutition).

Signs and symptoms of Tundikeri are enlargement of tonsils resembling fruit of cotton, mild to moderate throat pain, hyperaemia, fever, dysphagia, halitosis, and distaste in the mouth.[7] Tonsillitis and Tundikeri can be co-related as both have the same features.[8]

Tonsillitis, or Tundikeri, commonly encountered due to aaharaj hetu, means wrong dietary habits like junk food, food stored for a long time, cold food items, and cold beverages by vitiating predominantly kapha in mukha. In viharaj hetu, there is avoidance of dantdhawan (no brushing or brushing in a hurry) and no Kavala (gargling) count important in today's fast world. Sleeping in the prone position (avaksayanam) hinders the free flow of saliva, leading to malsanchaya hence vitiation of kapha dosha. Taking a bath daily after a heavy diet, excessive talking after eating, and suppression of natural urges aggravates vata, which in turn deranges kapha, thus congesting the channel of the oral cavity—lack of personal hygiene and more exposure to pollution cause recurrent infections.

In the present study, Trisamagutika will be given to group P (control group) and Kshargutika will be given to group Q (study group) for 15 days in two divided & recommended doses according to Young's rule. Assessment of subjective parameters will be done on the 0^{th}, 5^{th}, 10^{th}, and 15^{th} day and objective parameters will be before and after treatment with a one-year follow-up. If during treatment follow-up, recurrence occurs, then the decided intervention will be given to respected groups for three days. If signs & symptoms aggravate, treatment will be discontinued, and appropriate recommended treatment will be provided.

Need of Study:- Any infection in a growing child affects the immune system. Repeated attacks of tonsillitis hamper average growth and development. Resistance to antibiotics may develop due to the indiscriminate use of antibiotics in recurrent episodes. Recurrent episodes make the disease more vulnerable. Severe health hazards like laryngeal oedema, quinsy, hoarseness of voice, rheumatic fever, acute otitis media, and rheumatic arthritis disease are common complications.[9]

Recurrent attacks create an economic burden also. Lastly, a radical cure for recurrent episodes is Tonsillectomy.[10] But this is not the ultimate solution, as the tonsils are the body's first line of defence of the oropharyngeal gateway during childhood. The immunological role of the tonsils is to induce secretory immunity and regulate secretory immunoglobulins. Tonsil's established function is the production of lymphocytes. The immunological part of tonsils in preventing infections, complications involved with the tonsillectomy and age factors regarding growth & development are also to be considered against tonsillectomy. Therefore, it is necessary to search for an alternative, cost-effective feasible as well as potent with fewer side effects therapy.

There are many formulations have been mentioned in Ayurvedic texts for the treatment of Tundikeri. Kshargutika from Charaksamhita is one of the formulations to treat kanthgat roga.[13] But its effect on Tundikeri has yet to be scientifically evaluated. This study is designed to evaluate the efficacy of Kshargutika in the management of chronic tonsillitis in children. Whether it is more effective than Trisamagutika in the management of chronic tonsillitis as it contains ushna, teekshna dravya like panchkol & kshar, which have "Ksharan" effect (curetting & cauterisation effect). Trisamagutika from Kashyapsamhita has been already researched for its efficacy on tonsillitis in children. Trisamagutika showed significant results clinically as well as statistically with subjective & objective parameters and proved its efficacy. Trisamagutika's ingredients are mainly immunity enhancers and do shamanchikitisa. Shunthi is ampachak, vedanasthapak and deepani by property. Haritaki is called "Balbheshaj". Gulvel is called "Amruta". Both are Rasayan and Balya.In the paediatric age group, Trisamagutika seems to be more effective, potent and convenient than other formulations such as pratisaran aushadi like Gandhakdruti kalaki churna or Tankan bhasma pratisaran. According to the

growing age group in paediatrics, Trisamagutika seems more effective & can be given as lozenges than other formulations like guggul kashaya and avlehakalpana. According to Aacharya Sushruta, Tundikeri is a Bhedya roga. Therefore, all drugs should possess properties such as lekhana, shothhara, sandhaniya, ropana, raktastambhana and vedana sthapan. All ingredients of Kshargutika have the properties mentioned above, and Kshargutika is indicated as “Amruta” in mukhroga.

As in Ayurveda, the curative and preventive aspect is the basic principle; Kshargutika seems perfect to be proven for children as it is palatable, easy to administer, effective and potent. It works both; at the site of tonsillitis during chewing and internally when swallowed; both locally and internally.

According to Ayurveda, vitiation and imbalance of doshas (bodily humours), vata, pitta, and kapha cause, Tundikeri.[7,11,12] Mandagni & Vishamagni means impaired digestive function, and obstruction of channels (shrotovarodh) causes derangement of Kapha and Rakta, manifesting as difficulty in swallowing mouth breathing, and choking spells at night.[13]

This study will be carried out to explore the efficacy of Kshargutika in comparison with the efficacy of Trisamagutika in the management of chronic tonsillitis in children.[14] Proper modern treatment will be given during acute attack if it occurs in between the management duration (follow-up period) of chronic tonsillitis. References from Ayurvedic Samhitas for Kshargutika is Charaksamhita, chikitsasthan, trimarmiyaadhyay And for Trisamagutika is Kashyapsamhita, chikitsasthan, shothchikitsaadhyay[15, 16]

Kshargutika has action over vitiated doshas because of its anti-inflammatory, anti-microbial, immunomodulatory and rejuvenating properties. (Properties of ingredients)

Aims:-1.To Evaluate the comparative efficacy of Trisamagutika as standard control medicine versus Kshargutika as trial medicine in children with chronic tonsillitis.

2. To assess the recurrence of tonsillitis in terms of proportion in the reference of the control group (Trisamagutika) and trial group (Kshargutika) in children with chronic tonsillitis. **Objectives**: **- Primary**

1. To evaluate the efficacy of Trisamagutika in children with chronic tonsillitis on objective & Subjective parameters.
2. To evaluate the efficacy of Kshargutika in children with chronic tonsillitis on objective & Subjective parameters.
3. To evaluate the comparative efficacy of both Ksharagutika and Trisamagutika. in children with chronic tonsillitis on objective & Subjective parameters. **Secondary objectives**
4. To observe any adverse drug reaction of Kshargutika
5. To observe the prevalence of chronic tonsillitis with the Prakriti association of children

Trial Design: -This study is a double-blind randomised standard controlled comparative superiority study.

Methodology:-

Study setting:- The patients will be selected from OPD patients, IPD patients, camps & school health checkups by me at the Kaumarbhritya department of Mahatma Gandhi, DMIHER Ayurved College, Wardha.

Children with chronic Tonsillitis fulfilling inclusion criteria shall be randomly divided into two groups; 36 patients in each group. One group (P) will be given Trisamagutika and the other group (Q) will be given Kshargutika for 15 days orally B.D. Assessment will be done at 0,5,10 &15 th day. Followup will be taken every month for up to 1 year.

Guidelines:- CONSORT guidelines are used for the study

Case definition:- A child of 5-10 years suffering from either swollen tonsils, congestion in anterior pillars or enlarged, palpable, mobile, non-tender lymph nodes and fever $<101^0$F will be enrolled for this study.

Sampling procedure:-Children with chronic Tonsillitis fulfilling inclusion criteria shall be selected and randomly divided into two groups; 36 patients in each group. One group (P) will be given Trisamagutika and the other group (Q) will be given Kshargutika.

Randomization:-Randomization will be done according to the computer-generated random allocation software method to avoid bias in the study.

Concealment of allocation:- A third person will do coding to allocate subjects in sequentially numbered, opaque, sealed envelopes in groups P or Q (SNOSE scheme) to avoid bias in the study**.**

Type of Study:- Interventional study

Study Design:-This study is a double-blind randomised standard controlled comparative superiority study.

Inclusion criteria:-

- The age group of 5 to 10 yrs. of both sexes irrespective of socioeconomic class.
- Subjects presenting with two or more symptoms like
- 1. Kathin shoth (enlarged tonsils and or lymph nodes),
- 2. Ragatwa (hyperaemia),
- 3. Galoparodh (difficulty in deglutination),
- 4. mukhdourgandhya (halitosis),
- 5. Mand jwara (mild fever <100F)

Exclusion criteria: -

1. Tonsillitis patients with peritonsillar abscess, tonsillar cyst, and tonsillolith.
2. Subjects carrying complications of tonsillitis such as prediagnosed Rheumatic heart disease, Rheumatic fever
3. Patients who had taken systemic steroids in the past weeks.
4. Subjects with K/C/O HIV, TB, Hepatitis B, and Lower respiratory tract infection.
5. Subjects below 5yrs age and above 10 years of age

Withdrawal criteria: -

1. Those patients or their parents who don't want to continue or complete the study

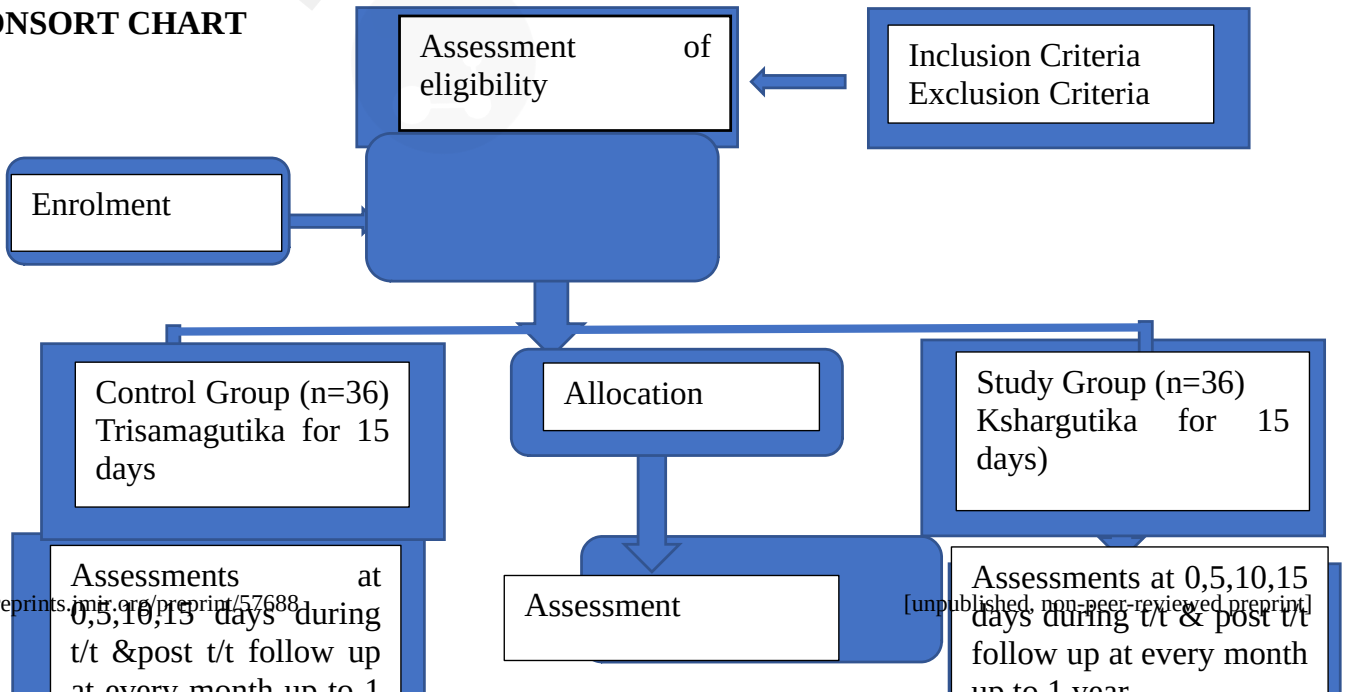
2. Development of any acute illness requiring hospitalisation

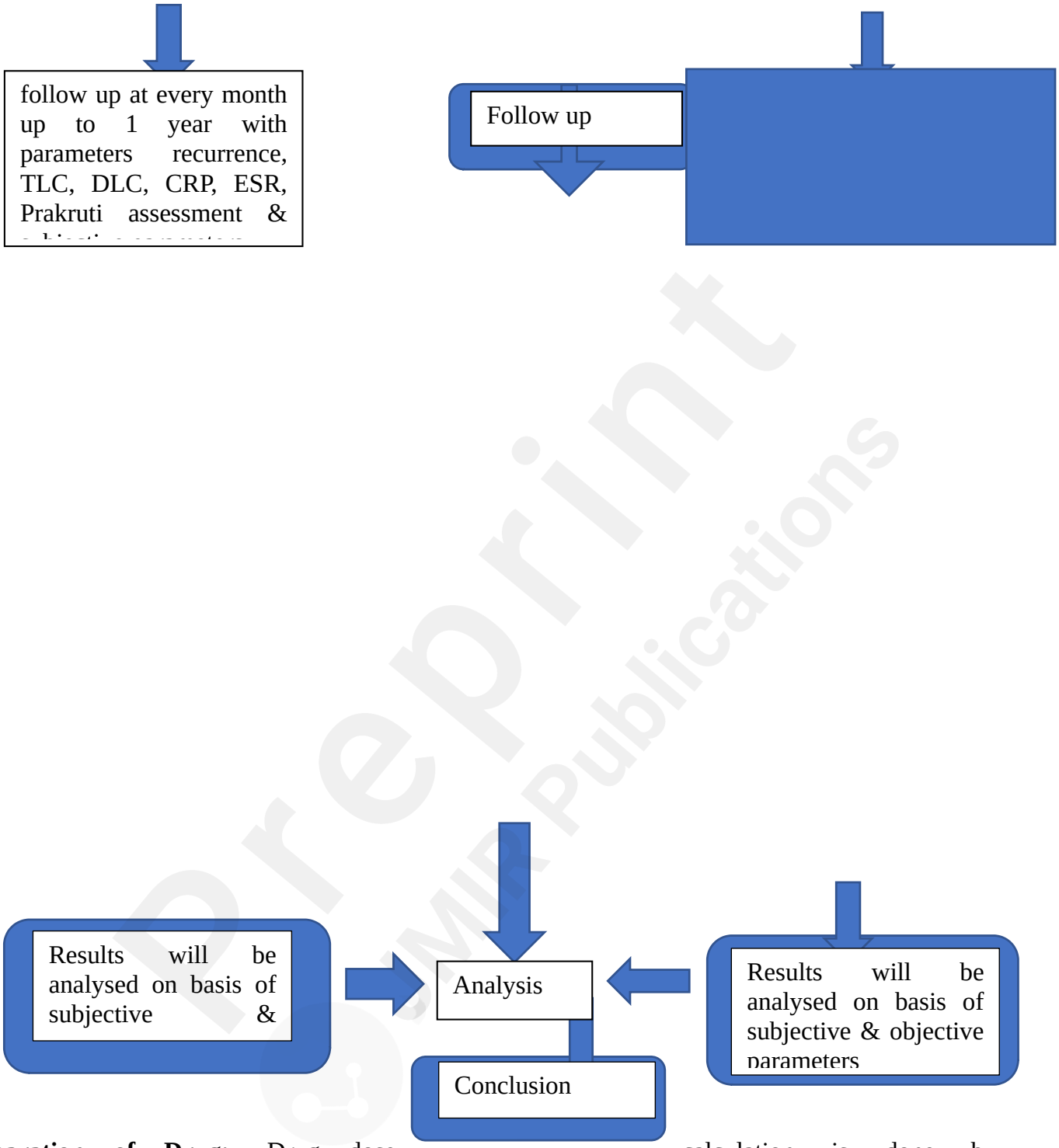
3. If the development of any untoward drug effect of the medicine is noticed, then the subject will be withdrawn from the study, & alternative suitable medicine will be provided free of cost.

Study Design

	Group P	**Group Q**
Subject	36	36
Name of Medication	Trisamagutika	Kshargutika
Dosage Form	The tablet form of the drug calculated as per age	The tablet form of the drug calculated as per age
Duration	Twice a day after a meal for 15 days	Twice a day after a meal for 15 days
Assessment	0,5,10,15th day	0,5,10,15th day
Follow up	Monthly up to 1 year	Monthly up to 1 year
Route/Mode of Administration	Oral	Oral

CONSORT CHART





Preparation of Drug:- Drug dose calculation is done by Young's formula according to age. As doses differ according to age, recommended doses will be given to patients. Gutikas of 150mg, 175mg, 200mg, 225mg, and 250 mg will be made & provided to maintain accurate dose.

The required contents of Trisamagutika & Kshar Gutika will be purchased from the Local Medical Shop raw materials, and its gutika will be prepared as mentioned in Sharangdhar Samhita.[17] It will be verified by the department. of Dravyaguna & Rasshastra.

Ingredients of the study drugs Kshargutika and Trisamagutika will be identified and authenticated by authorities of the Institute where the trial will be conducted. From the local market, the raw material will be purchased. The ingredients will be churned into fine powder & mixed in the recommended proportion. Then, Gutika will be made according to doses by instrument. Finally, Gutikas will be packed. All these processes will be verified and authorised by the concerned department.

Intervention modification:- If, during treatment, follow-up recurrence occurs, then a decided intervention will be given to respected groups for three days. If signs & symptoms are aggravating, then treatment will be discontinued, and proper recommended modern treatment will be provided in recommended doses.

Outcomes:- To compare the efficacy of both Ksharagutika and Trisamagutika. in children with chronic tonsillitis on objective & Subjective parameters.

Assessment criteria

Objective parameters: -

1. Recurrence in proportion
2. Total leucocyte count TLC on day 0 and day 15 and after six months or earlier recurrence 3. Neutrophils, lymphocytes, eosinophils DLC On day 0 and day 1
4. CRP
5. ESR
6. Prakruti assessment.
7. Kathin shoth (Enlargement of tonsils)
8. Ragatwa (Hypermia)
9. Lasikagranthi vrudhdhi (enlargement of lymph nodes)
10. Mukhdourgandhya(Halitosis)
11. Jwara (Fever)

Assessment by gradation 1 to 5 (absence to severe)[18]

1. Kathin shoth

1- No enlargement---Grade1
2- Enlarged within ant. tonsillar pillars--Grade-2
3- Enlarged within post. Pillars---Grade3
4- Enlarged beyond pillars---Grade4
5- Kissing tonsils with sleep apnoea---Grade5

2. Ragatwa (Hyperaemia)

1- Nil hyperaemia---Grade1

2- Hyperaemia of the surface of tonsils---Grade2

3- Pinkish appearance of pillars---Grade3

4- Hyperaemia of surrounding and pharynx---Grade4

3. Lasika granthi vruddhi (enlargement of lymph nodes)

1- Lymph nodes are not palpable. ----Grade1

2- Unilaterally palpable lymph nodes----Grade2.

3- Bilaterally /soft palpable lymph nodes----Grade3

4- Palpable lymph nodes bilaterally /hard---Grade4

5- Palpable lymph nodes bilaterally with tenderness---Grade5

4. Mukhdourgandhya (Halitosis): -

1. No bad breath---Grade 0
2. Bad breath when mouth open---Grade 1
3. Bad breath when talking---Grade 2

5. Jwara (Fever): -

1- No fever---Grade1

2- 98.6 to 100---Grade2

3 - 100 to 102---Grade3

4- >102---Grade

Subjective parameter: -

6. Galoparodh (Dysphagia)

1- No pain during swallowing----Grade1

2- Pain while swallowing solid food substances---Grade2

3- Pain during swallowing semisolid substances---Grade3

4- Pain while swallowing liquid food substances---Grade4

5- Continuous pain /unable to swallow---Grade5

Response Category: -

Responses will be assessed on the basis of relief of signs and symptoms. The response category is classified as mild, moderate and complete according to the rate of cure.

1. No improvement = 0 to 25% of signs and symptoms were cured.
2. Mild improvement = 25 to 50% of signs and symptoms were cured.

3. Moderate improvement = 50 to 75% of signs and symptoms were cured.
4. Complete improvement = > 75% of signs and symptoms were cured.

Analysis Plan

Statistical analysis: -

Statistical package for social sciences (SPSS) version 26 (SPSS Inc. Chicago, IL, USA) will be used. Observation and results will be computed statistically to know the significance level and obtain the conclusions of the Study Data will be analysed by a superiority trial applicable statistical Method. Confidence interval = 95%. The 15% difference in throat pain will be accepted as significant. A reduction in throat pain score by 20 will be considered significant.

Mann Whitney U test and the independent sample t-test for between subject's designs and paired samples t-test, Wilcoxon test for within-subject design will be done.

For the analysis of data, paired and unpaired t-tests will be applied respectively within the group, and comparison between groups and $P<0.05$ or $P<0.01$ will be considered statistically significant.

$P<0.001$ is highly significant, and $P>0.05$ is insignificant

Descriptive statistics: -

Percentage, standard deviation and mean score.

Univariate and multivariate analysis using the SPSS26 version with the approximate statistical method will be done to assess parameters. The data will be analysed by using Paired t-test, an unpaired t-test will be used for objective parameters, and the Wilcoxon test and one/two-way ANNOVA test for the subjective parameters.

For qualitative and quantitative analysis Chie square test and unpaired t-test will be applied, respectively.

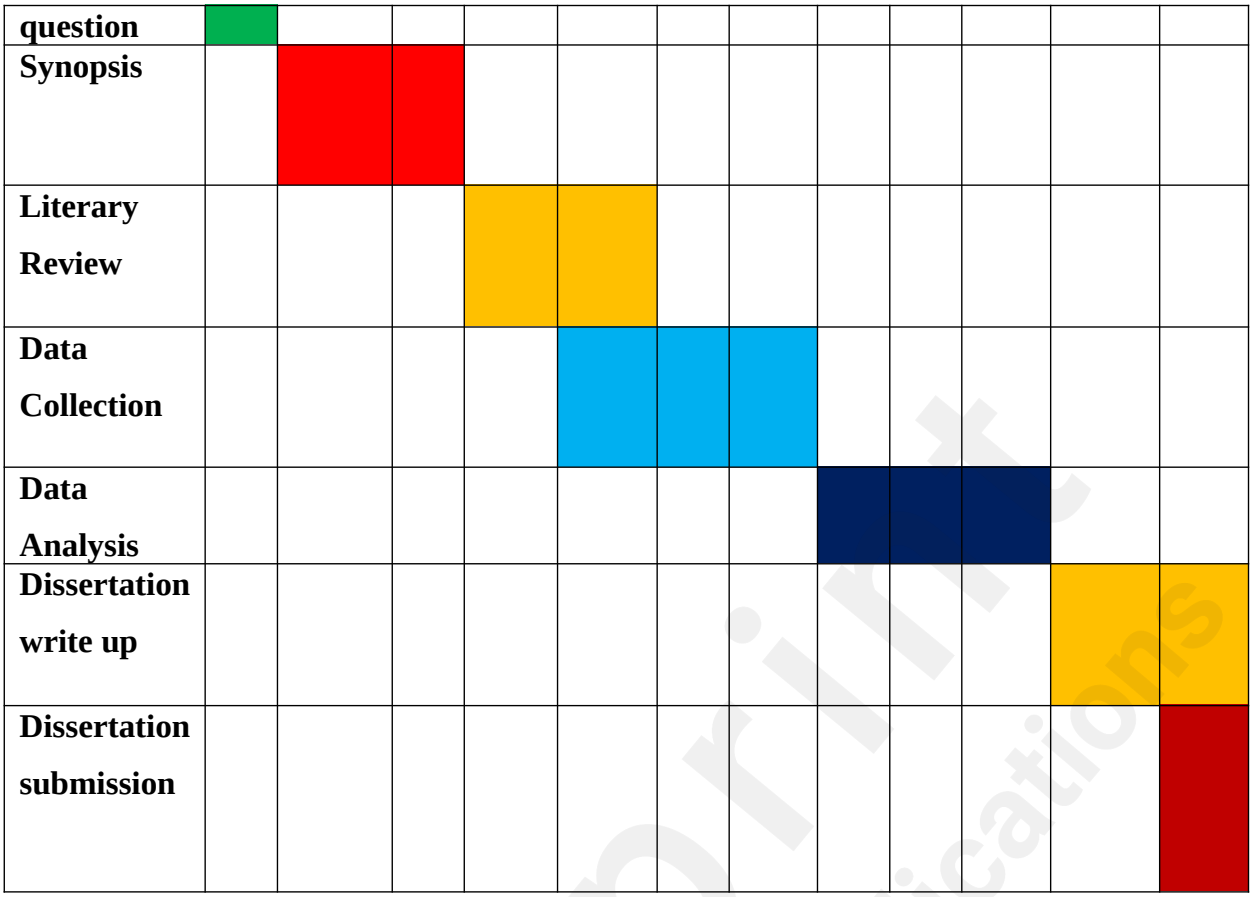
Participant timeline:-

Investigator:- Dr Sonali Dhumale

Title:- Evaluation of comparative efficacy of Trisamagutika versus Kshargutika in management of Tundikeri (chronic tonsillitis) in children: A Randomized Controlled Clinical Study

Gnatt chart:-

Timeline (Quarterly)	**Q1**	**Q2**	**Q3**	**Q4**	**Q5**	**Q6**	**Q7**	**Q8**	**Q9**	**Q10**	**Q11**	**Q12**
Title Research												



Study population: -

The study population includes children with chronic tonsillitis in the 5 to 10 years age group.

Source of data: -OPD patients, IPD patients, camps & school health checkups by me at Kaumarbhritya department of Mahatma Gandhi, DMIHER Ayurved College, Wardha.

Sample size & Sampling method: Sample Size: will be calculated after the pilot study using the formula for superiority Randomised controlled Trial.

$$N = 2 \times \left(\frac{z_{1-\alpha} + z_{1-\beta}}{\delta - \delta_0} \right)^2 \times s^2$$

N=size of per Group

Z= Standard normal deviation for one- or two-sided X

S^2= Polled standard deviation of both comparison group

δ = Clinically admissible margin of superiority

δ_o = A clinically acceptable margin.

Sample Size Calculation:

Considering the true difference between groups Treatment A & Treatment B for the Effect of throat pain relief=0

$$N = \frac{2 \times (Z_\alpha + Z_{\beta/2})^2 \times \sigma^2}{(\varepsilon - \delta)^2}$$

Mean Difference in reference treatment=1.53
Standard Deviation = 0.50
And clinically, relevant difference (δ)
1.53* (20/100)-0.306
(Assumed 20% decrease) as per reference
article values (€-δ)=(0-(-0.306) = 0.306
N= 2 *(1.64-0.84) ^{2} *(0.50)^2/(0.306)^2 =33 per group
Total N-66
(Zα at 5% level for equivalence (one-tailed) =1.64
$Z_{\beta/2}$: at 0.80 power =(1-β) at 15% =1.28.
36 in each group, including 10% dropout

Reference article:- Clinical study on the efficacy of polyherbal powder – Trisama churna in school-going children with Tundikeri (Tonsillitis)[19]

Sampling procedure:-Children with chronic Tonsillitis fulfilling inclusion criteria shall be selected and randomly divided into two groups; 36 patients in each group. One group (P) will be given Trisamagutika and the other group (Q) will be given Kshargutika.

Randomization:-Randomization will be done according to the computer-generated random allocation software method to avoid bias in the study.

Concealment of allocation:- A third person will do coding to allocate subjects in sequentially numbered, opaque, sealed envelopes in groups P or Q (SNOSE scheme) to avoid bias in the study**.**

Data collection tools and process:- Ayurved Samhitas, Modern textbooks, Dissertation, Case records, patient information registered records, written and informed consents

Online Search engines used: PubMed, Google Scholar, Research Gate, Shodh Ganga, Ayush Portal, Dhara Portal.

The search strategy used: Title and abstract & full text

Keywords: Tonsillitis, Tundikeri, chronic, children

Statistics outcome:- After the study data will be analyzed according to a suitable statistical test

Data Analysis (Statistical methods):- Collected data will be analyzed with the help of an inferential statistical test

Data monitoring formal committee:-

Ethical consideration:- Clearance from the Institutional Ethical Committee of Mahatma Gandhi Ayurved College, Hospital and Research Centre, Sawangi, Wardha has been taken,(Ref . no. MGACHRC/IEC/OCT-2022/582) and the project will be started only after receiving the permission and clearance certificate. The committee will decide on the endpoint and oversee the trial as it progresses.

The researcher will assess any adverse event and will report to the ethics committee. After getting

IEC, this study will be registered in CTRI

Consent:- Patient consent will be taken before conducting the trials in the local language while explaining every aspect of the study. The researcher will obtain consent from the trial participants.
The personal information of the participants will be collected and kept confidential before, during and after the trial. Physical data will be stored in a protected storage facility with only access to the researcher. Computerised data will be held in a password-protected hard drive with only access to the researcher**.**

Competing interests:- No competing interests will be disclosed

Dissemination:- This protocol will be further published as a thesis to disseminate the study for Tundikeri (Chronic tonsilitis). The study protocol provides a detailed overview of the study design, methodology, data collection procedures, data analysis plan and ethical considerations. By disseminating this protocol, we hope to advance knowledge in the field and facilitate future research.

Reporting guidelines:- CONSORT guidelines were used for the study

Data availability:- Underlying data:-No data is associated with this article.

Acknowledgements:- The experts whose works are cited and discussed in the manuscripts are acknowledged by the writers for their significant assistance. The writers also acknowledge the writers, editors and publishers of all the articles, books and journals that they used to review and discuss the literature for this project.

References: -

1. Kligman RM, Behram RE, Jenson HB, Nelson book of paediatrics, ed. 18th, New Delhi; Elsevier,2008:1757.
2. Kaplan EL, Top F H, Dudding B A, Waanamaker L W. Diagnosis of streptococcal pharyngitis differentiation of active infection from carrier state in symptomatic children. The journal of infectious diseases,123,5(1971):490-501
3. Woodford IT, Hanif J, Washband S, Hari CK, Ganguli LA. The effect of previous antibiotics therapy on the bacteriology of tonsils in children.
4. Bakar M A, Judy McKinn, Seraj Zohurul Haque, Md Anwarul Azim, Majumder, Mainul Haque, Journal of Inflammation Research, 2018;11;375 ncbi.nlm.nih.gov
5. Kishveet Sanjay P, All Ear, Nose and Throat disorders in paediatrics subject at a rural hospital in India, Australian Medical Journal AMJ 2015,3,12, p-786-790
6. Sharma P., Editor Sushrutsamhita, Nidansthan prakashan, Varanasi 21019 p.579
7. Paradkar H. Commentaries Sarvangasundara of Arunadatta and Ayurvedarasayana of Hemadri

on Astangahrdaya of Vagbhatt, Chaukhambha Orientelia Varanasi,2nd edition 2005, P 854

8. Susan S., Grey's Anatomy, pharynx chapter 35 the anatomical basis of clinical practice 39th edition, Philadelphia Elsevier 2005;619-631.
9. Gupta K vidyotini on Ashtanghriday of Vagbhatta, Yadunandan Upadhyay, Editor, Commentary Uttarsthan chapter 22. verse no. 54 1st edition, Varanasi Choukhambha prakashan, p719.
10. Gupte Suraj, The short textbook of Paediatrics, Jaypee Brothers medical publisher's Pvt. Ltd New Delhi 11th edition 2009;246
11. Trikamji VY, Acharya NR. Sushruta Samhita Sutrasthana 21/36. By Sushruta with Nibandhasngraha Commentary of Shri Dalhanacharya, Varanasi, Choukhamba Surbharti Prakashan. 2012.
12. Gupta K vidyotini on Ashtanghriday of Vagbhatta, Yadunandan Upadhyay, Editor, Commentary Uttarsthan chapter 22. verse no. 54 1st edition, Varanasi Choukhambha prakashan, p719
13. Upadhyay Y, 1stEd.), Madhawnidan-mukhrognidanam, shlok 34,49, Chaukhamba Surbharti Prakashan, Varanasi (2014)
14. Chavan G, Rathi R, Rathi B, Clinical study on the efficacy of Polyherbal powder- Trisama churna in school going children with tundikeri (Tonsillitis); European Journal of Molecular & Clinical Medicine,2020, vol 7, issue 11,318-27.
15. Tripathi B.(Ed.), Charak Samhita; Varanasi (1st ed.), Chaukhamba Surbharti Prakashan (2013)
16. Bhishagacharya S, Kashyap Samhita Sutra Sthana with Hindi commentary Vidyotini Reprint edition, Choukhmbha Sanskrit Series, Varanasi, Chap-25/4. P. 33.
17. Parashar R. Sharangadhar Samhita, Madhyam Khanda, Pratham adhyaya - 1/2. 3rd Edi. Nagpur: Baidynath publication, Nagpur; 1984.p.125.
18. Baghel M S & Rajgopala S., Developing guidelines for clinical research methodology in Ayurveda Institute for post-graduate teaching and research in Ayurveda, Gujarat Ayurved University (GAJ), Jamnagar, India, 2009, p.41
19. Chavan G, Rathi R, Rathi B, Clinical study on the efficacy of Polyherbal powder- Trisama churna in school going children with tundikeri (Tonsillitis); European Journal of Molecular & Clinical Medicine,2020, vol 7, issue 11,318-27.

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